

70467-3

12/20/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 20 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Kruti Dhyani, Regulatory Affairs Associate
Micrylium Laboratories
3309 Filmore Street, Suite A
San Francisco, CA 94123

Subject: BIOSURF
EPA Registration No.: 70467-3
Notification Date: July 03, 2013
EPA Receipt Date: August 21, 2013

Dear Ms. Dhyani:

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA and PR Notice 98-10.

Proposed Notification

- Adding two new packaging sizes for Retail Containers, (101.5 fl.oz (3000ml) and 169 fl.oz (5000 ml).

General Comments

Based on a review of the submitted materials, to add the two new packaging sizes are **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Campbell".

Jacqueline Campbell
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)



Application for Pesticide - Section I

1. Company/Product Number 70467-3	2. EPA Product Manager J. Campbell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIOSURF	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Micrylium Laboratories 3309 Filmore Street, Suite A San Francisco, CA 94123 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for addition of 2 new packaging sizes. 2 additional packaging sizes are 101.4 fl.oz and 169.1 fl.oz retail containers. Labels of 2 new packaging sizes are attached with the notification application for review. No other changes have been made to labelling or confidential statement of formula of this product. Please contact Kruti Dhyani for questions and provide an electronic response to kruti@micrylium.com or at +1(416)-667-0071 (fax)

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2 fl.oz, 16.9 fl.oz, 24 fl.oz, 101.5 fl.oz, 169 fl.oz, 202 fl.oz	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kruti Dhyani	Title Regulatory Affairs Associate	Telephone No. (Include Area Code) +1(416)-667-7040
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Associate	
4. Typed Name Kruti Dhyani	5. Date July 3, 2013	



July 3, 2013

Ms. Jacqueline Campbell, PM 34
Document Processing Desk (NOTIF)
Antimicrobial Division (7510P)
U.S Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S Crystal Drive,
Arlington, VA 22202

Re: BioSURF
EPA Reg. No.: 70467-3
Notification for addition of 2 new packaging sizes (101.5 fl.oz and 169 fl.oz)

Dear Ms. Campbell

Please accept this notification to add 2 new packaging sizes (Retail Containers) for the EPA registered product BioSURF. The 2 additional packaging sizes are 101.5 fl.oz and 169 fl.oz

No other changes have been made to the labeling or confidential statement of formula for this product.

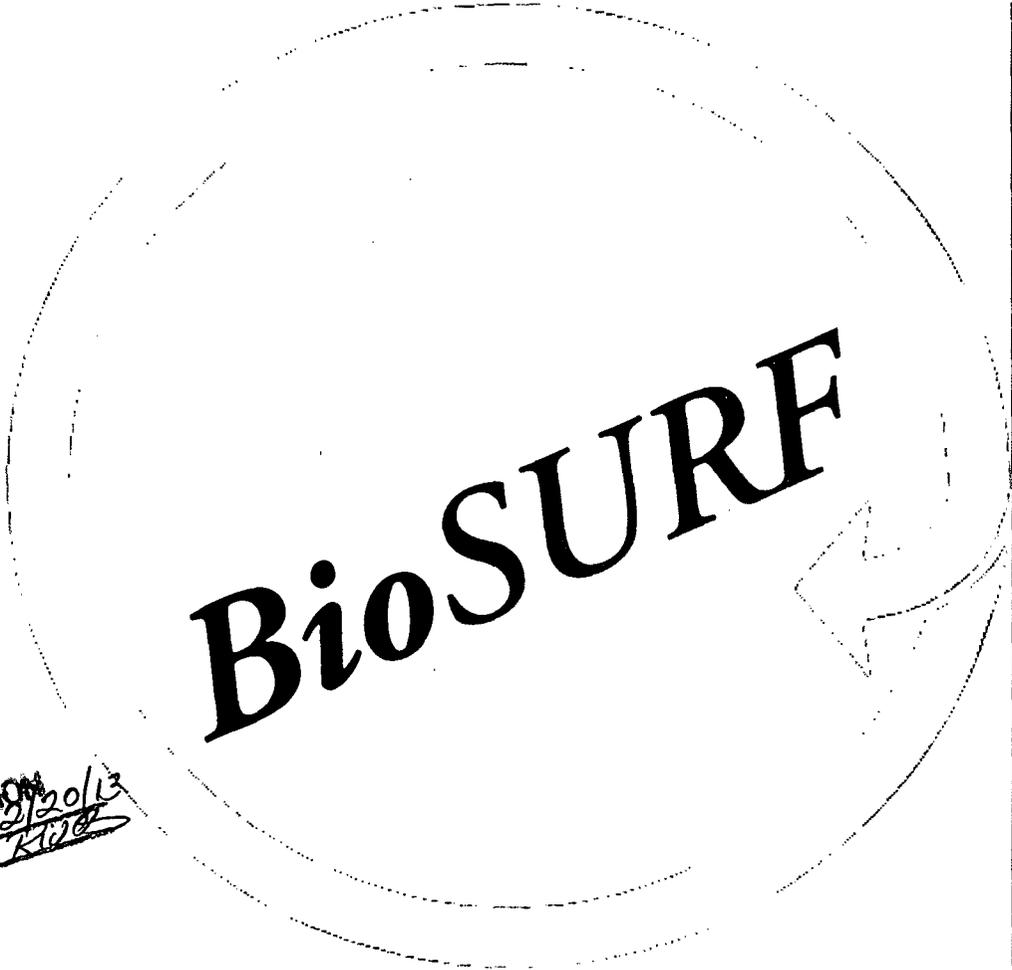
Please find attached:

- 1. Application for Notification; BioSURF (EPA Reg No.: 70467-3)
- 2. BioSURF Label for 101.5 fl.oz (3000mL)
- 3. BioSURF Label for 169 fl.oz (5000 mL)

Please Contact me at +1 (416)-667-7040 or at Kruti@micrylium.com, if you have any questions about this notification.

Sincerely,

Kruti Dhyani
Regulatory Affairs Associate
Micrylium Laboratories



NOTIFICATION
Data Reviewed: 12/20/13
Reviewed By: [Signature]

101.5 fl oz
3000 ml

EPA Registration Number 70467-3
EPA Establishment 070467-CAN-001

Micrylium
ISO13485:2003

Hospital Hard Surface Disinfectant

BioSURE is a ready to use hard surface disinfectant
for nonporous surfaces • One Step

<u>Active Ingredients</u>	
Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

Tuberculocidal-CanineParvovirucidal
Pseudomonacidal

CAUTION

READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN

5/7



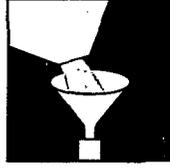
Aldehyde • NPE • Phenol Free

BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces

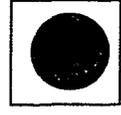
Directions for use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **BioSURF**™ kills Tuberculosis (*Mycobacterium bovis BCG*) and is Virucidal (*Canine parvovirus CPV-265*) in one minute in the presence of 5% bioburden. **BioSURF** kills *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* (formally *choleraesuis*) in 20 seconds in the presence of 10% bioburden. **BioSURF**™ kills *Trichophyton mentagrophytes* in 10 seconds in the presence of 10% bioburden. To effectively kill bacteria, fungi and inactivate canine parvovirus use **BioSURF**. Remove trigger from 24 fl oz spray bottle. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel. **BioSURF**™ is to be used on countertops and metal surfaces. May be used on wheelchairs, metal bed frames and exteriors of toilets. Spray all areas with a light mist. Maintain wetness for one minute to kill *Mycobacterium bovis BCG* and *Canine parvovirus CPV-265*. Maintain wetness for 20 seconds to kill bacteria and 10 seconds to kill fungi, then wipe with disposable paper towels or "Le Cloth™" towelettes.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



Flammable

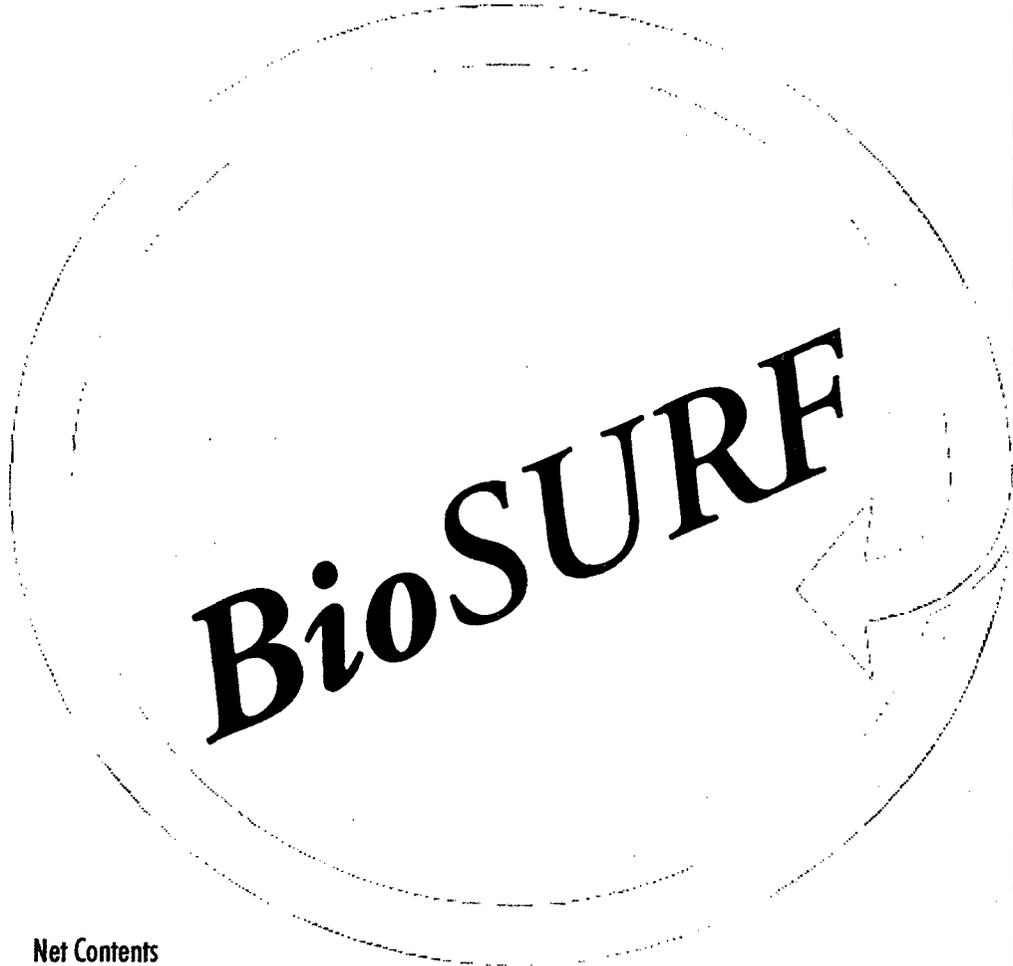


www.micrylium.com
3309A Filmore • 5000M Dufferin
San Francisco, CA 94123 • Toronto, Canada M3H5T5
1-800-489-8868

Manufactured by
Micrylium Laboratories

Precautionary Statements Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.
PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat or open flame. Keep out of the reach of children. DO NOT use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items. Do not apply this product in or on electrical equipment due to the possibility of shock hazard.
FIRST AID: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.
STORAGE & DISPOSAL: Do not contaminate water, food or feed by storage or disposal. **PESTICIDE STORAGE:** Do not store near open flame, at elevated temperature or in intense light. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.



Net Contents
169 fl oz
5000 ml

EPA Registration Number 70467-3
EPA Establishment 070467-CAN-001

Micrylium
ISO 13485 : 2003

Hospital Hard Surface Disinfectant
BioSURF is a ready to use hard surface disinfectant
for nonporous surfaces • One Step

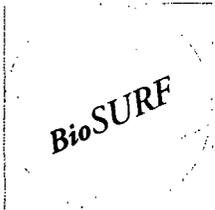
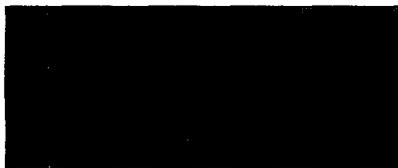
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CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.